

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IPD/P1174/WOD	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB98/01026	International filing date (day/month/year) 07/04/1998	Priority date (day/month/year) 11/04/1997
International Patent Classification (IPC) or national classification and IPC C12N9/02		
<p>Applicant THE SECRETARY OF STATE FOR DEFENCE et al.</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 4 sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input checked="" type="checkbox"/> Certain defects in the international application</li> <li>VIII <input checked="" type="checkbox"/> Certain observations on the international application</li> </ul>		

Date of submission of the demand 06/11/1998	Date of completion of this report 29.06.99
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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB98/01026

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-15 as originally filed

**Claims, No.:**

1-36 as received on 08/05/1999 with letter of 05/05/1999

**Drawings, sheets:**

1/9-9/9 as originally filed

2. The amendments have resulted in the cancellation of:

the description, pages:  
 the claims, Nos.:  
 the drawings, sheets:

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB98/01026

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-36
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

**2. Citations and explanations**

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item I**

**Basis of the report**

1. The amended set of claims filed with the letter dated 05.05.1999 appears to comply with the provisions of Articles 19(2) and 34(2)(b) PCT in that it does not extend beyond the disclosure in the application as filed.

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

2. The applicant's arguments with reference to item III of the first written opinion have been carefully considered. The IPEA is of the opinion that new claims 7, 13 and 17, are in deed adequately supported by the description since they relate to standard procedures and methods that can be carried out without the application of inventive skill. An opinion on the patentability of said claims is given in item V below.

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

3. The gist of the present application is that substitution of the amino acid corresponding to position 245 or 318 in *Photinus pyralis*, results in a mutant enzyme with a  $K_m$  higher than the wild-type. Recombinant luciferases with point mutations at amino acid 245 or 318 are not disclosed in the prior art, nor has the importance of these positions been anticipated. Thus, the recombinant luciferase of claim 1 as well as recombinant vectors, host cells and assays relating to the specific mutant variants appear to be both novel and inventive under the terms of Articles 33(2) and (3) PCT.

**Re Item VII**

**Certain defects in the international application**

- 4.1. To meet the requirements of Rule 5(1)(a)(ii) PCT, prior art document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.
- 4.2. Claim 19 appears to be redundant in light of preceding claim 18 and should thus be deleted in compliance with Rule 6(1)(a) PCT.
- 4.3. New claim 2 also appears superfluous in light of new claim 1 and should thus be deleted in compliance with Rule 6(1)(a) PCT.

**Re Item VIII**

**Certain observations on the international application**

- 5.1. New claims 1, 12 and 21 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not precisely defined. Said claims attempt to define the subject-matter in terms of the result to be achieved ("such that" and "capable of"), which merely amounts to a statement of the underlying problem (how to increase or decrease the luciferases  $K_m$  for ATP and how to improve thermostability and/or alter the wavelength of the emitted light). Such a definition is only allowed if the alleged invention cannot be defined in any other way. A protein however, can and must always be defined by its amino acid sequence and in the case of a mutant, by the amino acids to be substituted and the amino acids that take their place.